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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Office Action Summary	Application No. 09/394,519	Applicant(s) ZHANG ET AL.	
	Examiner Janet L. Epps	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *9-11,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,12-14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 4, received 6-04-01, is acknowledged. Applicants further Elected the following sequences for prosecution of Group I (claims 1-8, and 12-14) with traverse: SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157. The traversal is on the ground(s) that the inventions in Group I and Group II are related because the polynucleotide specifies an encoded polypeptide and the polypeptide is encoded by the polynucleotide. The Examiner agrees with Applicants that the polynucleotides of Group I can be used to produce the polypeptides of Group II. However, Applicant's arguments are not found fully persuasive, because the polynucleotides of the invention can also be used for diagnostic purposes. For example, the polynucleotides can be used to make hybridization probes to identify the presence of genes encoded by said polynucleotides in sample tissue. Additionally, the polypeptides of the instant invention can be made by a synthetic process, and can also be isolated directly from plant tissues. Therefore, the two inventions are distinct since either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Moreover, it can be further argued that the polypeptides and polynucleotides of the Groups I and II are unrelated inventions since they are structurally distinct chemical compounds having different properties and are used for different purposes.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 9-11 and 15-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4.

3. Claim 17 was not included in the Election-Restriction requirement mailed 2-27-01, this claim will be examined with elected group I.

4. Claims 1-8, 12-14 and 17 will be examined to the extent that the instant claims read on the elected sequences according to SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157

Claim Objections

5. Claim 1 recites the term "SEQ ID Nos." as a sequence identifier, the appropriate sequence identifier should be "SEQ ID NO:" See 37 CFR 1.821 through 1.825.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.**

7. Claim(s) 1-8, 12-14 and 17 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Claims 1-8 and 12-14 are drawn to isolated polynucleotides comprising a nucleotide sequence selected from the group consisting of (a) a nucleotide sequence encoding a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157; (b) a nucleotide sequence

encoding a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157, including substitutions, deletions or insertions; (c) a nucleotide sequence encoding a fragment from a polypeptide of (a) or (b); (d) a nucleotide sequence encoding a polypeptide comprising a sequence selected from the group consisting of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157; (e) a nucleotide sequence that has at least 40% identity with a nucleotide sequence of (a) or (b); (f) a nucleotide sequence having at least 60% identity with a nucleotide sequence of (c); (g) a nucleotide sequence comprising at least 15 consecutive nucleotides of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, or 157; and (h) a nucleotide sequence that hybridizes to a sequence encoding a polypeptide of (a), (b), or (c) under stringent conditions; vectors comprising said isolated poly-nucleotide, a host cell comprising said expression vector, a transgenic plant comprising or expressing said isolated polynucleotide, and a method of using said isolated polynucleotides.

The claimed polynucleotide compounds are not supported by a specific asserted utility because the disclosed use of the polynucleotides are not specific and are generally applicable to any polynucleotide. The specification states that the nucleic acid compounds may be useful as probes for assisting in the isolation of full-length cDNA, additionally the specification states that the polynucleotides of the invention comprise a nucleotide sequence encoding a transcription factor. Applicants define the term transcription factor as referring "to a polypeptide that controls the expression of a gene or genes either directly by binding to one or more nucleotide sequences associated with

a gene coding sequence or indirectly by affecting the level or activity of other polypeptides that do bind directly to one or more nucleotide sequences associated with a gene coding sequence. Additionally, Applicants state that said transcription factors may activate or repress expression of a gene or genes. Although, Applicants may have identified certain transcription factor domains in the polypeptides encoded by the claimed polynucleotides, Applicants have not provided any evidence that these polypeptides actually function as transcription factors nor have they identified the specific genes that are regulated by these polypeptides. Therefore, the Applicant's asserted utility is neither specific nor well established.

Further, the claimed polynucleotides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, according to the specification the claimed polynucleotides may be utilized to obtain a polypeptide. However, the polypeptide must then be used in conducting research to functionally characterize the polypeptide, i.e. to identify the specific genes that are regulated by said polypeptide that encodes a "transcription factor." The need for such research clearly indicates that the polypeptide and/or its function are not fully disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the polypeptides that are to be produced as final products resulting from processes involving the claimed polynucleotides have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to

characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or protein compound(s) such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8, 12-14 and 17 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

10. Claims 1-8, 12-14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8, 12-14 and 17 are drawn to isolated polynucleotide sequences comprising a nucleotide sequence selected from the group consisting of: SEQ ID Nos. 2N-1, where N=1-85 (Applicants have elected: SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, and 157). Additionally, the instant claims also read on isolated polynucleotide sequences that include substitutions, deletions or insertions of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, or 157; fragments of said sequences; nucleotides having at least 40% or 60% identity to said sequences; or comprising at least 15 consecutive nucleotides of SEQ ID NO: 19, 37, 43, 45, 47, 105, 123, 125, 127, or 157.

The claimed polynucleotides correspond to cDNA sequences isolated from *Arabidopsis thaliana*, wherein said sequences encode polypeptides that are putative transcription factors. The isolated polynucleotide sequences according to SEQ ID NO: 19, 37, 43, 45, 47, 105, 125, 127, and 157 meet the written description provisions of 35 USC 112, first paragraph. However, the instant claims are directed to encompass all polynucleotides that comprise substitutions, deletions, and insertions of said sequences. The instant claims also read on polynucleotide fragments, and all polynucleotide sequences having at least 40% or at least 60% identity to the sequence according to SEQ ID NO: 19, 37, 43, 45, 47, 105, 125, 127, or 157. Additionally, the instant claims read on nucleotide sequences having at least 15 consecutive nucleotides of SEQ ID

NO: 19, 37, 43, 45, 47, 105, 125, 127, or 157. The claimed sequences encompass all corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have an unspecified degree of identity (similarity, homology), and so forth. The specification provides insufficient written description to support the genus encompassed by the instant claims. Moreover, the instant claims do not recite any particular function that may be associated with the genus of sequences encompassed by the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the sequences corresponding to SEQ ID NO: 19, 37, 43, 45, 47, 105, 125, 127, and 157, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using

> "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 19, 37, 43, 45, 47, 105, 125, 127, and 157, but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

12. Claims 1-8, 12-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and those claims dependent thereon, claims 2-8 and 12-14, appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group is indefinite since it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925).

In the instant case claim 1 recites a nucleotide sequence selected from the group consisting of "(a) a nucleotide sequence encoding a polypeptide comprising a sequence selected from the group consisting of SEQ ID Nos. 2N-1, where N=1-85;.....(d) a nucleotide sequence encoding a polypeptide comprising a sequence selected from the group consisting of SEQ ID Nos. 2N-1, where N=1-85.." It appears that (a) and (d) of this Markush group are identical.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rounsley et al. (GenBank Accession No. B29089)

The following prior art is applied to the extent that it discloses polynucleotides encompassed by the claimed invention. It is further noted that the prior art does not disclose a specific, substantial or well-established utility for the polynucleotides of the instant invention.

Rounsley et al. discloses a sequence having at least 250 consecutive nucleotides of SEQ ID NO:19 of the instant invention. This sequence is disclosed as the genomic clone, T26B14, isolated from *Arabidopsis Thaliana.*

Rounsley et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

15. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman. (GenBank Accession No:T43527)

Newman discloses the cDNA clone, 120N14T7, isolated from *Arabidopsis Thaliana.* The cDNA sequence has the GenBank Accession No:T43527 and comprises at least 100 consecutive nucleotide sequences of SEQ ID NO: 127. This cDNA clone is in the lambda Zip-Lox vector.

Newman teaches each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

16. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated Newman. (GenBank Accession No: H76020)

Newman also discloses the lambda-PRL2 vector comprising the *Arabidopsis thaliana* cDNA clone 193M15T7. The sequence of this clone has a GenBank Accession No. of H76020, and comprises at least 50 consecutive nucleotide sequences from SEQ ID NO:43.

Newman teaches each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Newman. (GenBank Accession No: T14116)

Newman discloses the 2281 Lambda-PRL2 vector comprising the *Arabidopsis thaliana* cDNA clone 47E10T7. The sequence of this clone comprises at least 50 consecutive nucleotide sequences of SEQ ID NO:105.

Newman teaches each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

19. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by

Newman. (GenBank Accession No: AI100243).

Newman discloses the vector 34618 Lambda-PRL2 *Arabidopsis thaliana* cDNA clone 110C16XP 3', mRNA sequence. This sequence comprises at least 50 consecutive nucleotide sequences of SEQ ID NO:123.

Newman teaches each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 1, 5 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newman (GenBank H76020) in view of Newman et al.

Newman discloses the lambda-PRL2 vector comprising the *Arabidopsis thaliana* cDNA clone 193M15T7. The sequence of this clone has a GenBank Accession No. of H76020, and comprises at least 50 consecutive nucleotide sequences from SEQ ID NO:43.

However, Newman does not teach a method for identifying a homologous sequence to an isolated polynucleotide comprising a sequence according to claim 1.

Newman et al. teach high-throughput automated partial sequencing of anonymous cDNA clones isolated from Arabidopsis, and a comparison of the coding capacity of these expressed sequence tags (ESTs) with the sequences in the public

data bases results in assignment of putative function to a significant proportion of the ESTs.

It would have been obvious to one of skill in the art at the time of filing to use the cDNA clone having the GenBank Acc. No. H76020 of Newman in the method of Newman et al. It would have been obvious because the method of Newman et al. comprises the analysis of sequence data from partial sequencing of cDNA clones isolated from an *Arabidopsis* cDNA library and the sequence of Newman is based upon the *Arabidopsis* cDNA clone H76020. One of ordinary skill in the art seeking a potential use for said cDNA clone, would have been motivated to use the method of Newman et al. to identify sequences homologous to the sequence of H676020, in order to identify a putative function associated with the gene encoded by said sequence.

Therefore, the invention as a whole would have been *prima facie* obvious at the time of filing over Newman in view of Newman et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

jle
July 12, 2001